

**REMARKS**

**FORMAL MATTERS**

Claims 44-46 are pending in this application. Claims 44-46 have been rejected by the Examiner. Applicants have amended the specification to refer to the priority applications, which have now been granted as U.S. Patents or have now been abandoned, as requested by the Examiner.

**DEFINITENESS REJECTION**

The Examiner has rejected claims 44-46 as allegedly indefinite under 35 U.S.C. § 112, second paragraph, as improperly referring to Figure 6. Figure 6 was added during prosecution of the parent application and contains the *pol* sequence found in the specification on pages 25-28. Applicants have added Figure 6 to this application and argue that no new matter has been incorporated by the addition of the Figure. Applicants further request that the Examiner withdraw the definiteness rejection.

**WRITTEN DESCRIPTION**

The Examiner has rejected claims 44-46 as allegedly lacking written description support in the specification under 35 U.S.C. § 112, first paragraph. In particular, the Examiner is concerned about the scope of the terms "at least a portion of a *pol* gene," "at least a portion of the nucleic acid sequence of a *pol* gene," or "at least one domain in a *pol* gene of HIV-1<sub>BRU</sub>." The Examiner argues that the specification shows that applicants were in possession of the full-length *pol* gene and at least one fragment of another gene. The Examiner believes that Applicants were not in possession of a large

genus corresponding to *Pol* polypeptide fragments, nucleic acid sequences encoding them, or probes capable of hybridizing to the fragments under the recited conditions.

Applicants have considered the Examiner's remarks. The Examiner seems concerned that the specification recites particular fragments for the *gag* and *env* proteins in Example 6, but that the specification does not provide a sequence for a particular *pol* fragment. The Examiner does not seem to dispute that the specification provides support for (1) the full length *pol* sequence and (2) the concept that fragments were considered to be part of the invention. What the Examiner appears to require, instead, is a listing of particular *pol* fragments, along with their sequences, in the specification in order to allow a *pol* fragment claim.

The Examiner's standard is higher than the law requires. The Examiner cites cases such as *In re Rasmussen*, 211 U.S.P.Q. 323 (C.C.P.A. 1981), and *In re Wertheim*, 191 U.S.P.Q. 90 (C.C.P.A. 1976), for the proposition that the inventors must have had possession of the claimed invention at the time the application was filed. The Examiner seems to interpret these cases as requiring that the inventors were in physical possession of fragments of the *pol* gene and that the specification contain examples using the *pol* fragments as it has with the *gag* and *env* fragments.

None of the cited cases require that the inventors had a physical or actual reduction to practice of the claimed invention. It only requires that the inventors described the limitation as part of their invention. As constructive reduction to practice is sufficient for conception, it also can provide written description support for an invention. Applicants have stated in the specification that fragments are part of the

invention. The Examiner has not pointed to any specific statements that exclude fragments of *pol* from the invention. As Applicants have described fragments as being part of their invention, without limitation, the mere fact that Applicants have enumerated the nucleotide sequences for particular fragments of *env* and *gag* does not mean that the general disclosure of fragments does not apply to *pol*.

Contrary to the Office's statement's however, the Applicants were in possession of *pol* gene fragments. As previously discussed, Applicants have provided the full length sequence of the *pol* gene, spanning positions 1829-4936 (see specification Example 4, beginning on page 22). Combining this information with the description of the pROD4.8 plasmid carrying a 5 kb HindIII fragment that includes the full length *pol* gene (see page 13, lines 18-20) and with the restriction map of pROD4.8 in Figure 5, shows that different fragments of the *pol* gene can be isolated by digestions with BamHI and/or EcoRI and were envisioned as part of the invention.

Moreover, Figure 3B contains evidence that the inventors had *pol* gene fragments in their possession. Figure 3B depicts dots that correspond to the single stranded DNA form of M13 subclones from the HIV-1<sub>BRU</sub>. Their size and position on the HIV-1<sub>BRU</sub> cloned genome, determined by sequencing, is shown below the figure. From this figure, it is apparent that Applicants had two M13 subclones, No. 3 and No. 4, that contain two different internal domains or fragments of the *pol* gene and one clone, No. 5, that contains a part of the *pol* gene and a part of the Q gene. (See also description on pages 8 and 14.) Thus, the specification does include information on fragments of the *pol* gene and shows that certain fragments were in possession of the inventors.

Furthermore, it is not necessary to provide particular sequence information on the fragments included in the invention. The disclosure of the full length *pol* in combination with the information on *pol* fragments satisfies the requirements set forth by recent description cases, such as *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). That case required structural definitions of claimed DNA's, such as with sequence data. Here, as the inventors provided the full length sequence of *pol*, the fragment sequences can be deduced from the full length sequence. This is not a violation of the written description requirement, as the specification does not have to provide *ipsis verbis* descriptions of the limitation to satisfy the description requirement. *Union Oil Co. of Calif. v. Atlantic Richfield Co.*, 54 U.S.P.Q.2d 1227, 1235 (Fed. Cir. 2000). Additionally, all of the *pol* fragments share a common structural feature—their relationship to the full length sequence. *Lilly* instructs that common structural features can be used to provide written description support for a genus.

In conclusion, Applicants believe that the specification supports the concept of fragments, and does not limit it to those set forth in the Examples. Applicants request that the Examiner withdraw this rejection.

### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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